



K120553

NLT SPINE
eSpin

Traditional 510(k) Premarket Notification

510(k) SUMMARY

As required by 21 C.F.R. § 807.92

AUG 9 2012

Sponsor:

NLT SPINE Ltd.
6 Yad Harutzim St.
Kfar-Saba
Israel 44641

Contact Person:

Eti Zinger
Regulatory Affairs Director
NLT SPINE Ltd.
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Date Prepared: August 10, 2012

Name of Device: eSpin

Common or Usual Name: Arthroscope and Accessories

Classification Name: Arthroscope and Accessories
21 CFR §888.1100
Product Code HRX

Predicate Devices

- Spine View enSpire Discectomy System (K110992)

Intended Use / Indications for Use

The eSpin is intended for use in cutting and grinding intervertebral disc material during discectomy for fusion procedures in L2-S1 spinal segments in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by the history and radiographic studies. DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. The device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e. posterior pedicle screw and rod systems).



Technological Characteristics

The eSpin powered system consists of a hand-held instrument (manipulator unit), a set of disposable tips, and a motor adaptor. In addition, set of instruments are to access the disc space and to position the manipulator for discectomy. The eSpin needs to be connected to an Electrical Motor. The required motor specifications are provided in the eSpin User Manual.

Performance Data

Performance testing in bench and cadaver models demonstrated that the eSpin is substantially equivalent to its predicate.

Substantial Equivalence

The eSpin is as safe and effective as its predicate device. The eSpin has substantially similar indications for use and technological characteristics as compared to the predicate device. Any minor differences between the device and the predicate do not raise new questions of safety and effectiveness. The company's bench and cadaver testing demonstrate that the eSpin is as safe and effective as its predicate.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

AUG 9 2012

NLT Spine Limited
% Hogan & Lovells US, LLP
Mr. John J. Smith
555 Thirteenth Street, Northwest
Washington, District of Columbia 20004

Re: K120553
Trade/Device Name: eSpin
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope and Accessories
Regulatory Class: II
Product Code: HRX
Dated: August 09, 2012
Received: August 09, 2012

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

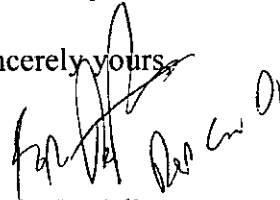
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



NLT SPINE
eSpin

Traditional 510(k) Premarket Notification

Indications for Use Statement

510(k) Number (if known): K120553

Device Name: eSpin

Indications for Use:

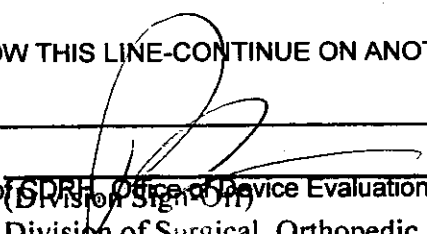
The eSpin is intended for use in cutting and grinding intervertebral disc material during discectomy for fusion procedures in L2-S1 spinal segments in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by the history and radiographic studies. DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. The device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e. posterior pedicle screw and rod systems).

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of 
(Division Sign Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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510(k) Number K120553

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